

### **Remarks**

The following remarks are in response to the Office Communication dated September 18, 2008.

#### **Summary of Claim Status**

Claims 34 and 48 are pending in this application. Claims 35-39 have been cancelled. Claims 40-47 were withdrawn. Claims 49-51 are newly added.

Claims 34 and 48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 52-54, 56, 57, 59-61 of pending Application No. 11/572,634 (the '634 application). Claims 34 and 48 are also rejected under 35 U.S.C. 102(a) as being anticipated by Business Wire.

#### **Summary of Claim Amendments**

In the interest of expediting prosecution, the Applicant has amended claims 34, 40, and 48. The above amendments to claims 34, 40, and 48 are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter.

Claim 34 has been amended to delete reference to framework regions and to limit the claim to CD20 binding molecules comprising a specific set of six complementarity determining regions (CDRs) selected from the CDRs recited in the previously presented claim 34. Support for this amendment is found, for example, in Table 3 of the specification as filed.

Claim 40, although withdrawn, has been amended identically to claim 34 in anticipation of rejoinder. Support for this amendment is also found, for example, in Table 3 of the specification as filed.

Claim 48 has been amended simply to replace the indefinite article "A" to the definite article –The- to reflect that claim 48 is a dependent claim.

Newly added claim 49 claims CD20 binding molecules comprising a specific set of six CDRs selected from the CDRs recited in the previously presented claim 34. The set of six CDRs are the CDRs shown in Table 3 as the six CDRs of the exemplary CD20 binding molecule AME 5. Therefore, support for this amendment is found, for example, in Table 3 of the specification as filed.

Newly added claim 50, which depends from claim 49, claims CD20 binding molecules having a specific light chain variable region and a specific heavy chain variable region. More particularly, the CD20 binding molecules claimed in claim 50 have a light chain variable region amino acid sequence and a heavy chain variable region amino acid sequence as shown in SEQ ID NO: 63 and 65, respectively. These amino acid sequences represent the light chain variable region and the heavy chain variable region of the exemplary CD20 binding molecule AME 5. Therefore, support for this amendment is found in Figure 6 A and Figure 7 A, for example.

Newly added claim 51 claims CD20 binding molecules having a specific light chain and a specific heavy chain. More particularly, the CD20 binding molecules claimed in claim 51 have a light chain amino acid sequence and a heavy chain amino acid sequence as shown in SEQ ID NO: 67 and 69, respectively. These amino acid sequences represent the light chain and the heavy chain of the exemplary CD20 binding molecule AME 33. Therefore, support for this amendment is found in Figure 10 A and Figure 11 A, for example.

No new matter is presented by the present amendments. Applicant respectfully requests entry of the amendments to the claims.

**Rejection under Judicially Created Doctrine of Double Patenting**

The Office Communication provisionally rejects claims 34 and 48 under the judicially created doctrine of obviousness-type double patenting over claims 52-54, 56, 57, 59-61 of the '634 application. Applicant respectfully traverses.

The instant claims 34 and 48 are directed to a CD20 binding molecule, i.e., an anti-CD20 antibody, or antigen binding fragment thereof, comprising a specific set of six CDRs (three light chain CDRs and three heavy chain CDRs). The claims 52-54, 56, 57, 59-61 of the '634 application are directed to humanized anti-CD20 antibodies comprising 1) the Fab AME 33 claimed in the instant claim 48 and 2) a human IgG1 Fc region variant that comprises an isoleucine, rather than a proline, at position 247. The anti-CD20 antibodies claimed in the '634 application demonstrate enhanced ADCC and decreased CDC activities, for example.

With respect to non-statutory obviousness-type double patenting, the U.S. Court of Appeals for the Federal Circuit (CAFC) recently stated the following:

The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of [a] patent for the same invention or an obvious modification thereof.” In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997). The judicially created doctrine of obviousness-type double patenting This doctrine “prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.” Eli Lilly & Co. v. Barr Laboratories Inc., 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001). In determining double patenting, a one-way test is normally applied, in which “the examiner asks whether the application claims are obvious over the patent claims.” In re Berg, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

*In re Basell Poliolefine Italia S.p.A.*, Fed. Cir., No. 2007-1450, p. 6, 11/13/08.

To establish a non-statutory obviousness-type double-patenting rejection, the Office must provide an analysis that parallels the guidelines for a 35 U.S.C. 103 obviousness determination (MPEP 804(II)(B)(1)). Furthermore, the recent USPTO guidelines for determining obviousness under 35 U.S.C. 103 state:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103

should be made explicit. The Court quoting *In re Kahn* stated that “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ ”  
Federal Register, 72(195), pp. 57528-57529 (Oct. 10, 2007).

The Office Communication did not meet this burden. Rather, the Office Communication relies on mere conclusory statements that the two sets of compositions claimed are not patentably distinct simply because they use the same VH and VL which binds CD20. The Examiner did not consider the invention as a whole, e.g., a CD20 binding composition comprising both a VH and VL and a human IgG1 Fc region variant that comprises an isoleucine, rather than a proline, at position 247. Consequently, the rejection should be withdrawn. Additionally, or alternatively, if the "provisional" nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the present application as a result of the amendments and arguments presented herein, while the “634 application is rejectable on other grounds, the Applicant respectfully requests that the Examiner withdraw the present nonstatutory obviousness-type double patenting rejection and permit the present application to issue as a patent without a terminal disclaimer in accordance with standard Patent Office procedures (see, MPEP 804 (I)(B)(1)).

**Rejection under 35 U.S.C. 102(a)**

Claims 34 and 48 are rejected under 35 U.S.C § 102 as being anticipated by a reference referred to by the Examiner in the outstanding Office Action, and hereafter, as the Business Wire reference. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Firstly, in order for a reference to anticipate a claim, it must show each and every feature of the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983). Furthermore, the identical invention must be shown is as complete

detail as is contained in the patent claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Stating its intention to clarify the law of anticipation, the CAFC recently held that “unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN, Inc. v. Verisign, Inc., et al.*, Fed. Cir., No. 2007-1565, pp. 17-18, 10/20/2008. The Applicant submits that the present anticipation rejection is improper because the Business Wire reference fails to teach each and every feature of the present claims arranged as recited therein, in as complete detail as is contained in the present claims. The presently claimed compositions comprise CD20 binding molecules featuring, at a minimum, a set of six CDRs each of which has a specific amino acid sequence. The Business Wire reference does not teach any of the required features of the present claims in as complete detail as is contained in the present claims because the Business Wire does not teach any amino acid sequences. Therefore, the Business Wire does not prove prior invention of the thing claimed and, thus cannot anticipate under 35 U.S.C. § 102.

In the Office Communication, the Examiner summarily concludes without reference to any rule or law, that the feature(s) of the claimed invention that Applicant asserts was not taught by the Business Wire reference, i.e., specific amino acid sequences of the claimed compositions, are inherent properties of the antibody mentioned in the Business Wire reference. The Examiner apparently therefore bases his rejection for anticipation under 35 U.S.C. § 102 on the doctrine of anticipation by inherency. In response, Applicant submits that the doctrine of anticipation by inherency, among other doctrines, enforces that basic principle that the public shall “remain free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the

underlying scientific principles which allow them to operate.” *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1348 (Fed. Cir. 1999). The evil policed by the doctrine of anticipation by inherency is not present in this case. In this case, even after the date of the Business Wire reference, the public was not free to make, use or sell the compositions that the present application claims because the public did not know how to do so. The public did not have knowledge of the feature(s) necessary to do so. The cited reference did not provide the public with the benefit of the presently claimed CD20 binding molecules. Until the publication of the present invention by the publication of the present application, the public would not have known how to make, use, or sell the claimed compositions.

Applicants further assert that any evidence introduced to provide descriptive matter not found in a single prior art reference must make clear that the property described by the extrinsic evidence is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill (*Continental Can*, 20 USPQ2d at 1749-50 (citing *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981)). Clearly, the specific amino acid sequences defining the claimed subject matter are not necessarily present in the compound described in the Business Wire reference. And certainly, one can not reasonably conclude that, based on the description in the cited reference, persons of ordinary skill would recognize that the specific amino acid sequences of the claimed subject matter were present in the AME-133 antibody. Accordingly, on the above basis, Applicants submit that the doctrine of anticipation by inherent anticipation is misapplied in the present rejection and should be withdrawn. Alternatively, if the Examiner persists with the rejection under 35 U.S.C. § 102(a) on the basis of the doctrine of anticipation by inherent anticipation, the Applicant kindly requests that he sustain that rejection, not by mere conclusory statements; rather, by some articulated reasoning with some rational underpinning, rule, or law to support the legal conclusion of anticipation by inherent anticipation.

Lastly, it is incontrovertible that “[a]n anticipating reference must be enabling; that is, the description must be such that a person of ordinary skill in the field of the invention can practice the subject matter based on the reference, without undue experimentation.” *Sanofi-Synthelabo v. Apotex, Inc.*, page 10 (Fed. Cir. 2008). A reference that is not enabling is not anticipating. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). The Business Wire reference fails to enable one of ordinary skill to make the presently claimed invention, i.e., a composition comprising a CD20 binding molecule comprising six CDRs each having a specific sequence. Importantly, the Business Wire reference merely names an anti-CD20 antibody, AME-133, that exhibits greater affinity and potency, *in vitro*, than Rituxan. By not including any sequence to the antibody or providing any reference to a publicly available deposit of the composition, the Business Wire reference fails to teach a person of ordinary skill in the field of the present invention how to make the antibody without undue experimentation. In other words, even with knowledge of the Business Wire disclosure a person of ordinary skill in the field of the present invention could not practice the claimed subject matter without any information of the antibody sequence(s) or a publicly available source of the composition without undue experimentation. If the Examiner persists with the rejection of any of the present claims under 35 U.S.C. 102(a) as being anticipated by the Business Wire reference the Applicant respectfully request that he communicate in detail his analysis and conclusions with respect to each of the Wands factors in order to support the Examiner’s conclusion that the cited Business Wire reference was an enabling prior art reference.

In view of the foregoing, Applicant submits that the Business Wire reference cannot properly anticipate the present claimed invention. Withdrawal of the present rejection under 35 U.S.C. 102(a) is believed to be in order, and is respectfully requested.

**CONCLUSION**

Applicant respectfully submits that all conditions of patentability are met in the pending claims as amended. Allowance of the pending claims is therefore respectfully requested.

If there are any outstanding issues regarding this response or application, the Examiner is invited to contact the undersigned attorney to resolve such issues, so that the claims may be allowed and issued without further delay.

Respectfully submitted,

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20 January 2008\_\_\_\_\_